YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 0068.4-2009

Medical endoscopes - Rigid endoscopes - Part 4: Fundamental requirements

医用内窥镜 硬性内窥镜 第4部分：基本要求

Issued on: May 1, 2023 **Implemented on: June 1, 2011**

Issued by: National Medical Products Administration

Table of Contents

Foreword

YY 0068 "Medical endoscopes - Rigid endoscope" is divided into four parts. - Part

1 Scope

YY 0068.4 sets the fundamental requirements for rigid medical endoscopes, the laparoscopes, arthroscopes, cystoscopes and sinuscopes through which a surgeon sees inside the body. It is Part 4 of the Chinese series and carries the requirements that apply across the class: the mechanical construction and its integrity, the materials, the resistance to the repeated autoclaving these instruments undergo between patients, the sealing that keeps fluid out of the optical channel, and the marking. A rigid endoscope that admits moisture fogs internally and cannot be repaired in theatre, which turns a scheduled operation into a cancelled one. Being a YY standard without the /T suffix, compliance is compulsory in China. The standard carries Amendment 1 of 2023.

This part of YY 0068 specifies the fundamental requirements for the rigid endoscope for medical purposes.

2 Normative references

The provisions in following documents become the provisions of this part through reference in this part. For the dated references, the subsequent amendments (excluding corrections) or revisions do not apply to this part; however, parties who reach an agreement based on this part are encouraged to study if the latest versions of these documents are applicable. For undated references, the latest edition of the referenced document applies.

GB 9706.1-2007 Medical electrical equipment - Part

3 Terms and definitions

The terms and definitions in the other parts of YY 0068 apply to this part.

4 General provisions

The safety and performance of rigid endoscopes shall be subjected to both preclinical and clinical evaluations, including appropriate risk analysis in accordance with YY/T 0316.

5 Optical and mechanical properties

The manufacturer shall ensure that the rigid endoscope meets the requirements of YY 0068.1 and 0068.2.If the endoscope also has other properties, the manufacturer shall provide the requirements AND provide the appropriate test methods for the intended purpose of the performance.

6 Electrical safety

Hard endoscopes shall comply with the applicable requirements of GB 9706.19. For endoscope with eyepiece cover, if its eyepiece cover is claimed to be electrically isolated from the insertion part, the dielectric strength of the isolated part shall pass a test at a sinusoidal voltage of

50 Hz with a maximum current not exceeding

0.03 mA at 1500 V. Test method shall be as specified in

20.4 of GB 9706.1-2007.

7 Biocompatibility

Materials of the part of the rigid endoscope inserted into the human body shall be subject to the biosafety assessment in accordance with the principles and requirements of GB/T 16886.1 to demonstrate good biocompatibility.

8 Interface security

As for the rigid endoscope with a cable interface for illumination, particularly an endoscope

with multiple interfaces other than an optical cable interface, in view of the possibility of other interfaces being incorrectly connected to the endoscope interface, the endoscope manufacturers shall implement the risk management procedures in accordance with YY/T 0316, in order to evaluate the physical possibility of incorrect connection to the endoscope interface, the likelihood of the operation occurring, and the severity of the potential harm to the patient.

9 Manufacturing

Endoscopes shall be produced in a manner that guarantees design characteristics.

10 Disinfection and sterilization

10.1 Endurance of repeatable disinfection or sterilization product For rigid endoscopes that can be repeatedly disinfected or sterilized, the method of disinfection or sterilization shall neither impair the functioning of the product NOR cause corrosion.

11 Packaging

Endoscopic packaging shall protect the endoscope from the effects of adverse storage and shipping conditions.

12 Marking and instruction manual

Rigid endoscope product markings and instruction manual shall comply with the provisions of other parts of YY 0068.